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Proposed Re-evaluation Decision

Bentazon

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the herbicide bentazon, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration for the sale and use of products containing bentazon in Canada.

An evaluation of available scientific information found that products containing bentazon do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of bentazon uses, new risk-reduction measures must be included on the labels of all products.

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products, to ensure they meet modern standards established to protect human health and the environment.

This proposal affects all end-use products containing bentazon registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for bentazon and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of bentazon.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

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[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Bentazon, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in the 1994 RED as well as in the USEPA Federal Register document, *Bentazon: Pesticide Tolerance,* 7 February 2002, the USEPA concluded that, bentazon was eligible for reregistration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in this RED were an adequate basis for the proposed Canadian re-evaluation decision.

For more details on the information presented in this Overview, please refer to the Science Evaluation section of this consultation document.

What Is Bentazon?

Bentazon is a herbicide that is used to control weeds in food/feed crops. Bentazon is also registered for weed control on turf (golf course, sod farm). Bentazon is applied using ground and aerial equipment by farm workers and professional applicators.

Health Considerations

Can Approved Uses of Bentazon Affect Human Health?

Bentazon is unlikely to affect your health when used according to the revised label directions. Additional risk-reduction measure statements are required on labels of bentazon products.

People could be exposed to bentazon by consuming food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only

uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that bentazon was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the situation in Canada, and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Bentazon is currently registered in Canada for use on the following commodities:

- soybeans;
- dry and snap common beans;
- dry edible beans (in the Red River Valley of Manitoba only);
- peas;
- lima beans;
- fababeans;
- corn (grain, silage, sweet and seed);
- flax (including low linolenic acid varieties);
- peanuts;
- blueberries;
- spring wheat (excluding durum); and
- snow peas.

As noted, bentazon may be used on other crops in other countries which are imported into Canada. MRLs for bentazon are established for the following commodities:

- peas at 3.0 ppm;
- beans at 0.5 ppm;
- barley, leeks, onions and wheat at 0.1 ppm; and
- blueberries, corn, flax, peanuts, rice and soybeans at 0.05 ppm.

Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Bentazon is Introduced into the Environment?

Bentazon is toxic to certain non-target terrestrial plants and birds; therefore, additional risk-reduction measures need to be observed.

Non-target organisms (e.g. birds, mammals, insects, aquatic organisms and terrestrial plants) may be exposed to bentazon in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of bentazon was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the situation in Canada, and equivalent risk-reduction measures are required. Furthermore, the PMRA will require terrestrial buffer zones for end-use products containing bentazon to protect terrestrial non-target plants from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of bentazon, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- A restricted-entry interval to protect workers re-entering treated sites

Environment

- Limitation to two applications per year for turf to reduce the potential for chronic risk to birds and to protect non-target plants
- Advisory label statement to reduce potential ground water contamination
- Buffer zones to protect non-target sensitive terrestrial plants

Next Steps

Before making a final re-evaluation decision on bentazon, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] document that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

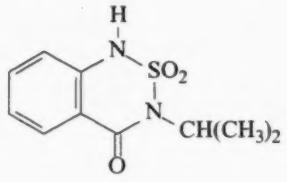
Bentazon is a selective postemergent herbicide, which acts by inhibiting electron transport during photosynthesis.

Following the re-evaluation announcement for bentazon, the registrant of the technical grade active ingredient in Canada indicated they intended to provide continued support for all uses included on the labels of commercial end-use products.

The PMRA used recent assessments of bentazon from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for bentazon, dated September 1994, as well as the USEPA Federal Register document *Bentazon: Pesticide Tolerance*, (TRED), 7 February 2002, (Volume 67, Number 26), can be found on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name	Bentazon
Function	Herbicide
Chemical family	Benzothiadiazione
Chemical name	
1 **International Union of Pure and Applied Chemistry (IUPAC)**	3-isopropyl-(1*H*)-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide
2 **Chemical Abstracts Service (CAS)**	3-(1-methylethyl)-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide
CAS Registry Number	25057-89-0
Molecular formula	$C_{10}H_{12}N_2O_3S$
Structural formula	

Molecular weight	240.3 amu
Purity of the TGAI	640 g/L (present as the sodium salt)

Based on the manufacturing process, the product is not expected to contain impurities of human health or environmental concern as identified in Regulatory Directive DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, Section 2.13.4 or Toxic Substances Management Policy (TSMP) Track 1 substances as identified in Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, Appendix II.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure	0.17 mPa (1.2×10^{-6} mmHg) at 20°C
Henry's law constant	7.167×10^{-5} Pa m^3 mol^{-1}
Solubility in water at 20°C	0.05 g/100 g
n-octanol–water partition coefficient	**pH** **log K_{ow} (25°C)** 5 0.77 7 -0.46 9 -0.55
Dissociation constant (p*K*a)	p*K*a = 3.3 at 24°C

2.3 Comparison of Use Patterns in Canada and the United States

Bentazon is a herbicide registered in Canada for selective post-emergence control of broadleaf weeds in corn (grain, silage, sweet and seed), soybeans, dry and snap common beans, peas, fababeans, lima beans, flax (excluding low linolenic acid varieties), forage sorghum, forage millet, peanuts, blueberries, spring wheat (excluding durum), snow peas, seedling forage legumes and seedling forage grasses, newly-planted fruit trees (apple, apricot, cherry, peach, pear and nectarine) and turf (sod farm, golf course). Bentazon is applied no more than twice a year with an application rate of up to 1.08 kg a.i./ha. Canada does not have any registered domestic end-use products containing bentazon, all end-use products are commercial products. The end-use products are formulated as solutions or suspensions. End-use products are applied using aerial or ground equipment by commercial applicators and farmers.

The American and Canadian use patterns were compared. The Canadian formulation type of end-use products and use sites are among those registered in the United States, with the exception of the following uses: blueberries, newly planted fruit trees (apple, apricot, cherry, peach, pear and nectarine—not considered food use), spring wheat (excluding durum), and flax (including low linolenic acid varieties). The registered uses in the United States on spearmint, peppermint, rice, pepper (chili type) do not exist in Canada.

In the United States, bentazon can be applied aerially to all use sites except ornamental lawn/turf (outdoor residential uses). Application methods in Canada include aerial and ground application. Bentazon is registered for aerial application in Canada only on soybeans, dry beans and snap common beans.

Based on this comparison of use patterns, it was concluded that the USEPA RED for bentazon is an adequate basis for the re-evaluation of uses of bentazon in Canada. All current uses are being supported by the registrant and were, therefore, considered in the re-evaluation of bentazon. Appendix I lists all bentazon products that are registered as of August 2007, under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 1994 RED, the USEPA concluded that the use of products containing bentazon registered at the time of the RED publication would not pose unreasonable risks or adverse effects to humans or the environment and, therefore, are eligible for reregistration. After the RED, the USEPA published a TRED in 2002, which includes an aggregate risk assessment that met the *Food Quality Protection Act* requirements.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

Exposure to bentazon may occur through consumption of food and water, working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers).

3.1.1 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating safety factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required. The toxicological endpoints selected by the USEPA for assessment of risk from occupational exposure are summarized in Appendix II.

Workers can be exposed to bentazon through mixing, loading or applying the pesticide, and when re-entering a treated site to conduct activities such as scouting and/or handling of treated crops.

3.1.1.1 Mixer/Loader/Applicator Exposure and Risk

Four dermal and inhalation exposure scenarios for mixer/loaders and applicators were identified, and were considered to be relevant to the Canadian situation, as follows:

1) Open mixing liquids for groundboom application;
2) Open mixing liquids for fixed-wing aerial application;
3) Groundboom application for open cab tractor;
4) Fixed wing aerial application for all cab types.

Handler exposure analyses were performed using the Pesticide Handlers Exposure Database (PHED) assuming baseline personal protective equipment (PPE) (i.e. long-sleeved shirt and long pants). Both short- and intermediate-term dermal and inhalation exposure were based on a maximum application rate of 2.24 kg a.i./ha, a 2% dermal absorption factor and the assumption that the inhalation absorption rate is 100%. An oral No Observed Adverse Effect Level (NOAEL) of 100 mg/kg bw/day based on a developmental toxicity study in the rat was used to assess short-term dermal and inhalation exposure and a NOAEL of 60 mg/kg bw/day based on a 13-week toxicity study in the rat was used to assess intermediate-term dermal and inhalation exposure. Other assumptions included a default body weight of 60 kg and a daily treatment area of 80 acres/day for groundboom application and 350 acres for fixed-wing aerial application.

Acceptable (i.e. >100) short-term combined dermal and inhalation MOEs ranged from 2857 to 100 000 for both private and commercial applicators. Intermediate-term combined dermal and inhalation MOEs for commercial applicators ranged from 1714 to 60 000 and were also found to be acceptable (i.e. >100). However, it was noted that bentazon is considered to be a potential skin sensitizer and the USEPA required a statement to be added to end-use product labels warning of the product may cause skin sensitization reactions in some people.

The RED adequately addressed exposure scenarios associated with the uses of products containing bentazon in Canada, and conclusions derived from the RED apply to the Canadian situation. Based on this, the PMRA requires that the statement "Potential skin sensitizer" must be added to all end-use product labels to further protect workers. Additional instructions concerning good hygiene practices are also required on labels. The proposed label amendments are listed in Appendix III.

3.1.1.2 Postapplication Exposure and Risk

The USEPA did not assess occupational postapplication risks to agricultural workers. In lieu of a postapplication risk assessment, a restricted-entry interval (REI) of 12 hours for all uses of bentazon within the scope of the Worker Protection Standard (i.e. agricultural use areas) was required. For all non-agricultural uses, a label statement prohibiting use until sprays have dried was required.

This was considered applicable to the Canadian situation, and the PMRA requires a 12-hour restricted-entry interval on all end-use product labels to further protect workers from postapplication exposure. Proposed label amendments are listed in Appendix III.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

Residential exposure is estimated using the MOE approach as explained for occupational exposure and risk assessment in section 3.1.1 above. The toxicological endpoints selected by the USEPA for assessment of risk from residential exposure are summarized in Appendix II.

In the United States, bentazon is registered for use on turf/lawn and ornamentals in residential areas (homes, parks, etc.). Risk to adult handlers and risk to adults and children from postapplication exposure (including incidental ingestion by toddlers) were assessed in a 2002 Federal Register document and are summarized below.

Because there were no chemical-specific nor site-specific data available to determine potential risk associated with residential exposure to bentazon, exposure estimates were based on assumptions and generic data as specified in the 1997 USEPA Standard Operating Procedures (SOPs) for Residential Exposure Assessments. Maximum application rates on labels were assumed to be used for all assessments.

Based on the use pattern, it was assumed that handler exposure was short-term only as bentazon is applied no more than twice per year. Since a dermal endpoint of concern for the short-term duration for handlers was not identified, the USEPA only considered inhalation exposure estimates to be relevant. Assuming that a homeowner treats his lawn and ornamental plants on the same day, the combined inhalation short-term MOE was estimated as 500 000 for the residential handler, which was not of concern (i.e. MOE >1000).

Based on the residential use pattern, the USEPA did not expect short- or intermediate-term inhalation postapplication exposure and did not expect long-term postapplication residential exposure. Due to the length of time bentazon was expected to remain in the environment (half-life of 24–65 days), both short- and intermediate-term residential postapplication dermal exposures were expected. However, a dermal endpoint of concern for short-term duration was not identified and only dermal intermediate-term postapplication exposure was assessed. Dermal intermediate-term postapplication exposure to adults from use on turf grass resulted in an acceptable MOE of 9100.

Short-term, non-dietary ingestion exposure for toddlers was not assessed by the USEPA because there was no acute dietary endpoint applicable to infants and children (the endpoint of concern was applicable only to women of child-bearing age). Intermediate-term dermal and non-dietary ingestion exposure to toddlers playing on treated turf is possible, and acceptable MOEs (i.e. >1000) of 6400 and 3500 for dermal/and hand-to-mouth exposures, respectively were calculated. The combined intermediate-term MOE for post-application residential exposure of toddlers (using both dermal and hand-to-mouth) was 2200.

The RED adequately addressed exposure scenarios associated with uses of bentazon (i.e. on golf course) in Canada; thus, the conclusions derived from the RED are considered applicable to the Canadian situation. Based on this, no further mitigation measures with respect to residential exposure are required.

3.1.2.2 Exposure From Food

Acute dietary risk is calculated considering the highest ingestion of bentazon that would be likely on any one day, and using food consumption and food residue values. The highest ingestion value is compared to the acute population adjusted reference dose (aPAD), which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake of residues is less than the aPAD, then acute dietary exposure is considered acceptable. The aPAD is based on a relevant endpoint from toxicology studies and on safety factors protective of the most sensitive subpopulation (see Appendix II).

An unrefined Tier I acute dietary risk assessment was conducted using the Dietary Exposure Evaluation Model (DEEM), which uses food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals from 1989–1992, resulting in <2% of the aPAD for the most sensitive subpopulation, females 13–50 years old, which was not of concern. This assessment was based on an aPAD of 0.1 mg/kg bw/day, which was calculated from a developmental toxicity study in the rat (NOAEL = 100 mg/kg bw/day) and a safety factor of 1000×. It was assumed that one hundred percent of each commodity was treated and that all residues were at tolerance levels.

Chronic dietary risk is estimated by determining how much of a pesticide residue may be ingested with the daily diet and comparing this potential exposure to an acceptable daily intake, which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects. The acceptable daily intake is referred to as the ADI in Canada, and, in the RED, it is expressed as the chronic population adjusted dose (cPAD). The ADI is based on a relevant endpoint from toxicology studies and on safety factors protective of the most sensitive subpopulation (see Appendix II).

A Tier I chronic dietary exposure analysis was conducted using the Dietary Exposure Evaluation Model (DEEM), which uses food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals from 1989–1992, resulting in a cPAD of 28% for the most sensitive sub-population of children 1–6 years old, which was not of concern. This assessment was based on an cPAD of 0.003 mg/kg bw/day, which was calculated from a 1-year feeding study in the dog (NOAEL = 3.2 mg/kg bw/day) and a safety factor of 1000×. The calculations were performed with some refinements including anticipated residues for succulent peas and percent crop treated for certain commodities (mint, sweet corn, peas (snap, green, dry), dry beans, alfalfa, sorghum, corn, rice, peanuts, soybeans and potatoes). Although the surveys indicated no use of bentazon on alfalfa, sorghum and potatoes in the United States, the USEPA used a value of 1% crop treated in their chronic dietary exposure analysis. Tolerance level residues and 100% crop treated were assumed for the remaining commodities.

The registered food uses of bentazon in Canada are encompassed by those assessed in the USEPA 2002 Federal Register document, with the exception of spring wheat (excluding durum), blueberries, and forage millet.

Despite the differences between the use patterns in the United States and in Canada, conclusions derived by the USEPA regarding risk to dietary exposure to bentazon are considered relevant to the situation in Canada based on the following:

- The maximum application rate for crops in the United States is 2.24 kg a.i./ha, whereas in Canada it is 1.08 kg a.i./ha. In Canada and the United States, applications to most crops are made no more than twice a year.

- In their acute assessment, the USEPA assumed tolerance level residues, 100% crop treated (CT) and DEEM default processing factors for all commodities. This resulted in 2% or less of the aPAD being occupied by dietary exposure from food for females 13–50 years old (the most sensitive subpopulation). There is sufficient room left in the risk cup to accommodate for any differences between the use patterns in Canada and the United States.

- In their chronic assessment, the USEPA assumed tolerance level residues for all crops but succulent peas, and 100% crop treated for all crops except mint, sweet corn, peas (snap, green, dry), dry beans, alfalfa, sorghum, corn, rice, peanuts, soybeans and potatoes. Where values of 0% CT were found, the USEPA assumed 1% CT. This resulted in 28% of the cPAD being occupied by dietary exposure from food for children 1–6 years old (the most sensitive subpopulation). Based on this analysis, it was concluded that chronic dietary risk was not of concern. There is sufficient room left in the risk cup to accommodate for any differences between the use patterns in Canada and the United States.

Therefore, the USEPA assessment is considered applicable to the situation in Canada.

3.1.2.3 Exposure From Drinking Water

The lifetime Health Advisory (HA) level of 20 ppb was used as the representative national ground water screening concentration for both acute and chronic scenarios. The Tier II Pesticide Root Zone Model/Exposure Analysis Modelling System (PRZM/EXAMS) was used to calculate estimates of bentazon concentrations (bentazon + its metabolite 2-amino-N-isopropyl benzamide, AIBA) in surface water with an estimated environmental concentration of 41 ppb for acute and 8 ppb for chronic exposure. These surface and ground water estimates were then compared to back-calculated drinking water levels of comparison (DWLOCs) and found to be acceptable, with the acute surface water EEC of 41 ppb and the acute ground water EEC of 20 ppb both less than the acute DWLOC of 2900 and the chronic surface water EEC of 8 ppb and the chronic ground water EEC of 20 ppb both less than the chronic DWLOC of 95.

3.1.2.4 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to bentazon (i.e. from food, water and non-occupational exposures).

Acute and chronic aggregate risk were comprised of contributions from food and drinking water exposures and were found to be acceptable (see section 3.1.2.3). Short-term aggregate risk resulted in an acceptable MOE of 250 000 combining food and residential exposure and the surface water (8 ppb) and ground water (20 ppb) EECs did not exceed the short-term DWLOC of 3000. Similarly, intermediate-term aggregate risk resulted in acceptable MOEs of 8200 (females 13–50 and males 13+) and 1900 (children aged 1–6) combining food and residential exposure and the surface water (8 ppb) and ground water (20 ppb) EECs did not exceed the intermediate-term DWLOCs of 340 (females 13–50), 64 (children aged 1–6) and 400 (males 13+) .

The registered food and residential uses of bentazon in Canada are encompassed by those assessed in the USEPA 2002 Federal Register document, with the exception of spring wheat (excluding durum), blueberries, and forage millet. Despite these differences between the American and Canadian use patterns, conclusions derived by the USEPA regarding risk to dietary exposure to bentazon are considered relevant to the situation in Canada (see Section 3.1.2.2). Furthermore, in Canada, use on turf is limited to sod farms and golf courses. The USEPA assessment of aggregate risk included a residential exposure component, which would be sufficient to address golfer exposure.

Overall, the Canadian aggregate exposure scenarios were adequately addressed by the USEPA aggregate risk assessment. Therefore, the USEPA aggregate exposure conclusions are considered applicable to the uses of bentazon in Canada and no further mitigation measures are required.

3.1.3 Cumulative Effects

The USEPA has not determined whether bentazon has a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, it was assumed that bentazon does not share a common mechanism of toxicity with other substances, and a cumulative risk assessment was not required.

3.2 Environment

3.2.1 Environmental Risk Assessment

The two major routes of dissipation for bentazon are through surface runoff and leaching through the soil. Based on laboratory studies, bentazon is not considered to be persistent. Terrestrial field studies indicated that bentazon dissipates rapidly ($t_{½}$ <33 days) under typical use conditions. The soil degradates of bentazon include 2-amino-N-isopropyl benzamide (AIBA), which is very mobile but non-persistent and N-methylbentazon which is not mobile. There was no available data to persistence in the environment of N-methylbentazon.

Statements required by the USEPA on their bentazon end-use product labels as a result of the RED document include a ground water advisory statement and a statement prohibiting the direct application of bentazon to aquatic habitats.

To assess the ecological risk of bentazon to both terrestrial and aquatic non-target plants and animals, the USEPA calculated risk quotients (RQs) based on appropriate toxicity endpoints and EECs and compared the resulting RQs to corresponding levels of concern (LOCs).

For both avian species and mammals, EECs were calculated based on typical food consumption parameters by various species followed by application rates of 0.84 kg a.i./ha to 4.0 kg a.i./ha per season. The maximum single label rate in the RED was 2.24 kg a.i./ha, and labelling allowed several applications per season. The maximum seasonal cumulative rate for bentazon was calculated as 3.6 kg a.i./ha. Based on the maximum cumulative rate of 3.6 kg a.i./ha, LOCs for non-endangered birds were not exceeded for any scenario. Although the LOC was exceeded for endangered species of grazing birds, the USEPA concluded that endangered grazing birds would not likely be acutely affected because most would not inhabit areas where bentazon is used. The EPA determined that there was a potential for chronic risk to birds although an RQ could not be calculated due to the lack of a NOEL. With respect to mammals, acute RQ's did not exceed LOC's at any application rate assessed and acute oral and subacute dietary risk to mammals from bentazon were not expected. Bentazon was determined to be practically non-toxic to honey bees, and therefore low risk to non-target insects was expected as a result of exposure to bentazon.

Aquatic EECs were calculated assuming 2 applications of 2.24 kg a.i./ha. The USEPA did not specify what model was used to calculate aquatic EECs. Minimal acute risk to both fresh water and estuarine/marine aquatic fish and invertebrates was expected. Chronic risk to aquatic animals was not anticipated because of the relatively low exposure values when compared to the acute toxicity test results.

LOCs were not exceeded for aquatic plants assuming 2 applications of 2.24 kg a.i./ha. However, LOCs were exceeded for terrestrial plants for all registered uses (i.e. at rates as low as 1.12 kg a.i./ha). The highest risk resulted from runoff to areas containing semi-aquatic plants after 2 applications of 2.24 kg a.i./ha.

The USEPA concluded that there was potential for chronic risk to birds and risk to terrestrial and semi-aquatic plants from registered uses of bentazon. To reduce the potential for chronic risk to birds and to terrestrial and semi-aquatic plants, the USEPA required all bentazon labels be amended to reflect a maximum seasonal application rate of 2.24 kg a.i./ha. In addition, in order to minimize spray drift from the target site, and to minimize the effects on non-target organisms, the USEPA prepared spray drift labelling statements for all products containing bentazon that might be applied aerially to agricultural crops.

The American use pattern for bentazon encompasses the Canadian use pattern, and the USEPA's risk-reduction measures should be applied to Canadian products containing bentazon. The rate reduction to reflect a maximum seasonal application rate of 2.24 kg a.i./ha is not relevant to Canada since the maximum seasonal application rate in Canada is already only 2.16 kg a.i./ha. The USEPA's mitigation measures must be adapted to the Canadian situation as follows.

- A ground water advisory statement.

- An environmental hazard statement to not apply the end-use product directly to any aquatic habitat.

- The current Canadian label for Bentazon (Basagran), Registration No. 12221, does not specify how many applications to turf are allowed in one year. To reduce the potential for chronic risk to birds and risk to terrestrial plants, the registrant is required to amend the label to reflect a maximum of two applications per year for turf use.

- The PMRA will require terrestrial buffer zones for bentazon end-use products to protect terrestrial plants from spray drift. Proposed label amendments are listed in Appendix III. Inputs to buffer zone models are described in Appendix IV.

3.2.2 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the 1995 federal Toxic Substances Management Policy (TSMP), which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

The federal Toxic Substances Management Policy and PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, were taken into account during the re-evaluation of bentazon. The PMRA has reached the following conclusions.

- Bentazon is not bioaccumulative. The *n*-octanol–water partition coefficients (log K_{ow}) are 0.77 at pH 5, -0.46 at pH 7, and -0.55 at pH 9, which are all below the TSMP Track 1 cut-off criteria of ≥5.0. Bentazon is not a candidate for Track 1 classification.

- Based on a review of the available chemistry information (see Section 2.0), the technical product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive DIR98-04 or TSMP Track 1 substances as identified in Regulatory Directive DIR99-03, Appendix II.

Formulant issues are being addressed through PMRA formulant initiatives and Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document,* published on 31 May 2006.

4.0 Proposed Re-evaluation Decision

The PMRA has determined that bentazon is acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and the environment. The labels of Canadian end-use product must be amended to include the label statements listed in Appendix III. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

End-use products that contain more than one active ingredient under re-evaluation will be eligible for continued registration only when all of those other active ingredients are determined to be eligible.

5.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and DACO tables can be found on our website at www.pmra-arla.gc.ca. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra_infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document for bentazon is available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

The USEPA document *Bentazon; Pesticide Tolerance* (Federal Register: 7 February 2002, Volume 67, Number 26) is available through the USEPA's website at www.epa.gov/fedrgstr/EPA-PEST/2002/February/Day-07/p2984.htm

List of Abbreviations

ADI	acceptable daily intake
a.i.	active ingredient
AIBA	2-amino-N-isopropyl benzamide
amu	atomic mass unit
aPAD	acute population adjusted dose
ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
bw	body weight
CAS	Chemical Abstracts Service
cPAD	chronic population adjusted dose
cRfD	chronic reference dose
CSFII	Continuing Survey of Food Intakes by Individuals
CT	crop treated
DACO	data code
DEEM	Dietary Exposure Evaluation Model
DWLOC	drinking water level of concern
EC_{25}	effective concentration at 25%
EC_{50}	effective concentration at 50%
EEC	estimated environmental concentration
EXAMS	Exposure Analysis Modeling System
FCID	Food Commodity Intake Database
FIRST	FQPA Index Reservoir Screening Tool
FQPA	*Food Quality Protection Act*
g	gram(s)
GAP	good agricultural practice
ha	hectare
HA	Health Advisory
ISP	integrated system product
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	*n*-octanol—water partition coefficient
L	litre(s)
LC_{50}	median lethal concentration
LOC	level of concern
LOD	limit of detection
m	metre(s)
m^3	metre(s) cubed
mg	milligram(s)
mm	millimetre(s)
mm Hg	millimetre mercury
MOE	margin of exposure
mol	mole
mPa	millipascal(s)
MRL	maximum residue limit
NAQWA	National Water Quality Assessment Program

NOAEL	no observed adverse effect level
NOEL	no observed effect level
Pa	Pascal
PDI	potential daily intake
PGW	Prospective Ground Water
pH	-log 10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
p*K*a	-log 10 acid dissociation constant
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
PRZM	Pesticide Root Zone Model
PVC	polyvinyl chloride
RED	Reregistration Eligibility Decision
REI	restricted-entry interval
RQ	risk quotient
SCI-GROW	Screening Concentration In Ground Water
SF	safety factor
SOP	Standard Operating Procedures
TRED	Tolerance Reassessment Eligibility Decision
TSMP	Toxic Substances Management Policy
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Registered Products Containing Bentazon as of 7 August 2007

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
12221	Commercial	BASF Canada Inc.	Basagran Liquid Herbicide	Solution	480 g/L
16641	Commercial	BASF Canada Inc.	Laddok Herbicide	Suspension	200 g/L bentazon 200 g/L atrazine
20898	Technical	BASF Canada Inc.	Technical Bentazon (Basagran)	Solution	640 g/L
22006	Commercial	BASF Canada Inc.	Basagran Forte Liquid Herbicide	Solution	480 g/L

Appendix II Toxicological Endpoints for Bentazon Health Risk Assessments

Exposure Scenario (route and period of exposure)	Dose (mg/kg bw/day)	Study	Target UF/SF or MOE [a]
Acute dietary[b] (females 13–50 years of age)	Developmental NOAEL = 100	Developmental toxicity study (rat)	1000
	aPAD = 0.1 mg/kg bw/day		
Chronic dietary[b] (all populations)	Oral NOAEL = 3.2	1-year feeding study (dog)	1000
	cPAD = 0.003 mg/kg bw/day		
Short-term inhalation[b] (residential)	Oral NOAEL = 100	Developmental toxicity study (rat)	1000
Intermediate-term dermal and inhalation[b] (residential)	Oral NOAEL = 13.1 (dermal absorption factor of 2%)	1-year feeding study (dog)	1000
Short-term dermal and inhalation[c] (occupational)	Oral NOAEL = 100	Developmental toxicity study (rat)	100
Intermediate-term dermal and inhalation[c] (occupational)	Oral NOAEL = 60	13-week feeding study (rat)	100

[a] UF/SF refers to total of uncertainty and/or safety factors for dietary assessments. MOE refers to desired margin of exposure for occupational or residential assessments.

[b] From USEPA Federal Register document (7 February 2002)

[c] From USEPA RED (1994)

Appendix III Label Amendments for Products Containing Bentazon

Canadian end-use product labels should be amended to include the following statements to further protect workers and the environment.

I) On the primary display panel of all end-use product labels, the following statement must be added:

POTENTIAL SKIN SENSITIZER.

II) The **DIRECTIONS FOR USE** section of end-use product labels must be amended to specify a maximum number of applications of two per year to turf.

III) The following statements should be included in a section entitled **PRECAUTIONS**.

Potential skin sensitizer.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

DO NOT enter or allow worker entry into treated areas for 12 hours following application.

IV) The following statements should be included in a section entitled **ENVIRONMENTAL HAZARDS**.

The use of this chemical may result in contamination of ground water particularly in areas where soils are permeable (e.g. sandy soil) and/or the depth to the water table is shallow.

DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), estuarine/ marine habitats.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

TOXIC to non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

V) For the product with Reg. No.12221, the following statements must be included in a section entitled **DIRECTIONS FOR USE.**

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 8 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing or rotorspan.

Buffer zones:

Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer, inter-row hooded sprayer, spot treatment, soil drench, and soil incorporation.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands).

Method of Application	Crop		Buffer Zones (metres) Required for the Protection of: Terrestrial Habitat
Field sprayer*	Snow peas, peas (field and processing), seedling forage grasses/legumes and established forage legumes (for seed production)		1
	Turf, soybeans, corn, peanuts, beans (snap, lima, faba), dry beans, flax, newly planted fruit trees, blueberries, spring wheat, alfalfa, seedling forage legumes/grass ( )		2
Aerial	Dry common beans	Fixed and rotary wing	20
	Soybeans, snap beans	Fixed wing	35
		Rotary wing	30

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

VI) For the product with Reg. No.16641, the following statements must be included in a section entitled **DIRECTIONS FOR USE**.

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air."

Buffer zones:

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrublands).

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:
		Terrestrial Habitat
Field sprayer*	Corn (silage, grain, sweet, seed)	2

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

VII) For the product with Reg. No. 22006, the following statements must be included in a section entitled **DIRECTIONS FOR USE**.

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground."

DO NOT apply by air.

Buffer zones:

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrublands).

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:
		Terrestrial Habitat
Field sprayer*	Forage sorghum and forage millet	1
	Soybeans, corn, dry beans, fababeans, peas, flax	2

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

Appendix IV Inputs to Buffer Zone Models

Ground Use Data (from Canadian labels)				
Crop	**Formulation Type**	**Method of Application**	**Number of Application**	**Maximum Cumulative Seasonal Application Rate (g a.i./ha)**
Registration No. 12221				
Turf, soybeans, corn, peanuts, beans (snap, lima, faba), dry beans, flax, newly planted fruit trees, blueberries, spring wheat	Liquid	Field sprayer (ASAE medium)	2	1680 (2 × 840)
Peas (field and processing), seedling forage grasses/legumes and established forage legumes (for seed production)	Liquid	Field sprayer (ASAE medium)	1	1080
Snow peas, dry edible beans in the Red River Valley of Manitoba (when tankmixed with Reflex)	Liquid	Field sprayer (ASAE medium)	1	840
Registration No. 16641				
Corn (silage, grain, sweet, seed)	Liquid	Field sprayer (ASAE medium)	2	1600
Registration No. 22006				
Soybeans, corn, dry beans, fababeans, peas, flax	Liquid	Field sprayer (ASAE medium)	2	1680 (2 × 840)
Forage sorghum and forage millet	Liquid	Field sprayer (ASAE medium)	1	1080

Model Input Data for Aquatic Buffer Zones (from 1994 RED)		
Half-life for aquatic buffer zones	Water	2.63 days
Choice of toxicity endpoint for freshwater buffer zones	*Selenastrum capricornutum*	1/10 EC_{50} = 0.45 mg a.i./L
Choice of toxicity endpoint for marine buffer zones	Eastern oyster embryo larvae	1/10 EC_{50} = 10.9 mg a.i./L

Model Input Data for Terrestrial Buffer Zones (from 1994 RED)		
Half-life for terrestrial buffer zones	Soil degradation half-life	14 days
Most sensitive terrestrial plant species EC_{25} for vegetative vigour	Cabbage—Vegetative vigour	EC_{25} = 45 g a.i./ha

Aerial Use Data (from Canadian labels)				
Crop	**Formulation Type**	**Registration No.**	**Number of Applications**	**Maximum Application Rate (g a.i./ha)**
Soybeans, snap beans	Liquid	12221	2	1080
Dry common beans	Liquid	12221	1	1080

Product Information for Aerial Use	
Parameter	**Value**
	Registration No. 12221
Aircraft type	Fixed and/or rotary
ASAE spray quality	Medium
Carrier	Oil
Product guarantee (g a.i./L)	480
Specific gravity of end-use product (g/L)	1192
Minimum spray volume (L/ha)	50
Water content of product (%)	54.6
Wind speed (km/h)	8
Temperature (°C)	25
Relative humidity (%)	50